

Remarks

Claims 1-12 and 21-20 are currently pending.

Claims 1 and 21 have been amended to recite a sequence identity of 95%. Support for this amendment can be found in the specification on page 13 at lines 35-27. Thus, no new matter has been added.

Claims 10 and 30 have been amended to address a formality. Thus, no new matter has been added. Claim 30 has also been amended to clarify that the seeds and plant parts comprise the construct in their genome and, thus, do not constitute a product of nature. Support for this can be found in the specification on page 18 at lines 1-6 and in the Examples. Thus, no new matter has been added.

The specification has been amended conform to the date indicated on the ADS.

Claims 1-12 and 21-30 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It was stated in the Office Action, on page 3-4, that "[t]he Applicants do not describe any polynucleotides having at least 75% sequence identity to at least 200 nucleotides of SEQ ID NO:4 other than SEQ ID NO:4 that when transformed into a plant would reduce the ration of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant . . . Since the genus of polynucleotides has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims".

Attention is kindly invited to the specification, page 13 at lines 24-37, which states that the

polynucleotide sequences used for suppression do not necessarily have to be 100% complementary to the polynucleotide sequences found in the gene to be suppressed. For example, suppression of all the subunits of the soybean seed storage protein β -conglycinin has been accomplished using a polynucleotide derived from a portion of the gene encoding the α subunit (U.S. Patent No. 6,362,399). β -conglycinin is a heterogeneous glycoprotein composed of varying combinations of three highly negatively charged subunits identified as α , α' and β . The polynucleotide sequences encoding the α and α' subunits are 85% identical to each other while the polynucleotide sequences encoding the β subunit are 75 to 80% identical to the α and α' subunits. Thus, polynucleotides that are at least 75% identical to a region of the polynucleotide that is target for suppression have been shown to be effective in suppressing the desired target

Accordingly, one of ordinary skill in the art would realize that modest changes to the nucleotide sequence of a stem-loop structure would not be expected to alter its ability to down-regulate expression of the gene of interest.

Given the amendment of claims 1 and 21 and the above discussion, withdrawal of the rejection of claims 1-12 and 21-30 under 35 U.S.C. § 112, first paragraph, is respectfully requested

Claims 1-12 and 21-30 were rejected under 35 U.S.C. § 112, first paragraph, on the ground that the specification allegedly does not reasonably provide enablement for a method for utilizing a stem-loop construct comprising a polynucleotide with at least 200 nucleotides having at least 75% identity to SEQ ID NO:4.

The above discussion combined with the amendment of claims 1 and 21 are believed to be equally apposite with respect to this ground of rejection.

It was stated on page 5 of the Office Action that "[t]he Applicants do not teach transformed plants that have a reduced ratio of liquiritigenin-derived isoflavones relative to liquiritigenin-derived isoflavone levels in an untransformed plant. The state-of-the-art is such that one of skill in the art cannot predict the range of reduction of liquiritigenin-derived isoflavones when there is no control for comparison and the prior art teaches that the range of liquiritigenin-derived isoflavones can vary dramatically from cultivar to cultivar. . . . the Jack variety of Soybean of the instant Application was not included in the Wang study that Applicant recites".

It is respectfully noted that liquiritigenin-derived Isoflavone levels in non-transformed soybean plants (variety Jack) and null-segregants (variety Jack) were known to one of ordinary skill in the art and were described in the August 2003 issue of Phytochemistry (Oliver Yu et al. Phytochemistry 63(2003) 753-763.

It is stated in this article on page 760, section 4.2, that "Soybean (cv Jack) embryogenic suspension cultures were transformed" and on page 759, Figure 6 a null-segregant (a transformed plant that does not contain the transgene) designated as "PCR: -" indicates that the ratio of daidzin + glycitin + genistin (grey and white bars)/ TOTAL isoflavone levels (black bar) is about 43. The ratio of liquiritigenin-derived isoflavones to total isoflavone levels can also be derived from five individual control soybean plants illustrated in Figure 2, page 755 of Yu et al. (and range from about 40 to 50 and average at about 46 with a standard deviation of about 5.

Thus, it is well known in the art that the range of liquiritigenin-derived isoflavone levels can vary widely, however, the *ratio* of liquiritigenin-derived isoflavone levels to total isoflavone levels in wild type soybean varies less and is documented in the art as described above. The ratio of multiple transgenic plants described in Table 4 on page 29 of the specification show a substantial decrease in *ratio* of liquiritigenin-derived isoflavones relative to total isoflavone levels when compared to the ratio (of 46 +/- 5) of the same soybean cultivar Jack described in Yu et al.

It was also stated on page 6 of the Office Action that "Table 1 of Wang shows levels of genistein, daidzein, and glycitein that represent a summation of all free and conjugated forms, while those Applicant presents are measured levels of genistin, daidzin and glycitin not genistein, daidzein, and glycitein. It is entirely unclear what kind of comparisons Applicant is trying to make given that the range of results presented on average do not fall outside the range of what happens to be the normal-derived isoflavone levels".

A comparison of the result set forth in Table 4 and Figures 3 and 4 of the instant specification with the results set forth in Table 1 Wang et al. JAOCS 77:483-487, was set forth in Example 3 and is discussed page 32 of the specification to further demonstrate that the ratio of liquiritigenin-derived isoflavones relative to total isoflavone levels is well known to one skilled in the art.

As stated on page 26, line 7 of the specification, "Seeds were ground, the combined powder was extracted with methanol, hydrolyzed with base, and analyzed. Base hydrolysis converts both malonylglucoside conjugates and acetylglucoside conjugates into glucoside conjugates (genistin, daidzin, and glycitin). Total glucoside conjugates are then measured. While aglycones are not measured by this method the amount of aglycones present is in such low quantities as to not affect the final results."

Thus, this indicates that the total glucoside conjugates measured by the method set forth in Example 3 of the instant specification represent a summation of all conjugated forms but not the free forms (aglycones). Since free forms are present only in very low quantities, the measurements set forth in Table 4 on pages 29-31 of the specification can be directly compared to the measurements set forth in Table 1 of Wang. This comparison demonstrates that instant invention does indeed disclose

transgenic soybeans with a reduced ratio of liquiritigenin-derived isoflavones relative to total isoflavone levels.

Accordingly, withdrawal of the rejection of claims 1-12 and 31-30 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

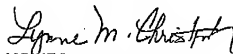
It is believed that the rejection of claim 30 under 35 USC §101 has been obviated in view of the amendment of this claim.

It is respectfully submitted that the claims are now in form for allowance which allowance is respectfully requested.

A Petition for a one (1) month extension of time accompanies this Response along with a copy of the Yu et al. article.

Please charge any fees or credit any overpayment of fees which are required in connection with the filing of this Response to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,



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Dated: June 11, 2007